HFD-613

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 5 1998

NDA 11-835/S-060

Merck & Co., Inc.
Attention: Jeffery R. White, M.D.
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Dr. White:

Please refer to your December 3, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HydroDiuril (hydrochlorothiazide) Tablets.

We acknowledge receipt of your submission dated August 21, 1998.

This supplemental new drug application provides for final printed labeling revised to add information relating to the dosing of this product in the pediatric population as required by the December 13, 1994 Federal Reaister notice entitled: "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of 'Pediatric Use' Subsection in the Labeling."

The following changes were made:

1. The **PRECAUTIONS/Pediatric Use** subsection has been changed from:

   Safety and effectiveness in children have not been established.

   to:

   There are no well-controlled clinical trials in pediatric patients. Information on dosing in this age group is supported by evidence from empiric use in pediatric patients and published literature regarding the treatment of hypertension in such patients. (See **DOSAGE AND ADMINISTRATION, Infants and Children).**

2. Under the **DOSAGE AND ADMINISTRATION/Infants and Children** subsection, "(See **PRECAUTIONS, Pediatric Use)"** has been added to the end of the section.

We also note that the following additional changes were made:

Under **DESCRIPTION:**

1. The molecular weight of hydrochlorothiazide has been updated to 297.74 based on the IUPAC 1995 Standard Atomic Weights.

2. Reference to the 100 mg strength was deleted from this section.

Under HOW SUPPLIED:

1. Text was added to describe the tablet codings accurately.

2. Reference to the 50 mg bottles of 1000 was deleted as this size is no longer available.

3. Reference to the 100 mg tablet strength was deleted as this strength is no longer marketed.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your August 21, 1998 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 5945332

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
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